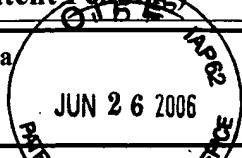


AF  
ZMW

**TRANSMITTAL LETTER**  
**(General - Patent Pending)**

Docket No.  
 RPP156cUS

In Re Application Of: **Yasmin Thanavala**



Application No. 09/464,414	Filing Date 12/16/1999	Examiner Michele C. Flood	Customer No. 24041	Group Art Unit 1655	Confirmation No. 7502
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**Title: ORAL IMMUNOLOGY USING A PLANT PRODUCT CONTAINING A NON-ENTERIC PATHOGEN ANTIGEN**

**COMMISSIONER FOR PATENTS:**

Transmitted herewith is:

- (1) Reply Brief**
- (1) Acknowledgment Postcard**

in the above identified application.

- No additional fee is required.
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- The Director is hereby authorized to charge and credit Deposit Account No. **50-0822** as described below.
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Signature

Dated: **June 20, 2006**

Michael L. Dunn  
 Registration No. 25,330  
 Simpson & Simpson, PLLC  
 5555 Main Street  
 Williamsville, New York 14221  
 Phone: (716) 626-1564  
 Facsimile: (716) 626-0366

I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to the "Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450" [37 CFR 1.8(a)] on **June 20, 2006**

(Date)

Signature of Person Mailing Correspondence

**Michael L. Dunn**

*Typed or Printed Name of Person Mailing Correspondence*

cc: **MLD/ALB**



Attorney Docket No. RPP156CUS  
U.S. Patent Application No. 09/464,414  
Date: June 20, 2006

## IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

U.S. Patent Application No.:09/464,414

Confirmation No.: 7502

Applicant(s): Yasmin Thanavala

Filed: December 16, 1999

For: ORAL IMMUNOLOGY  
USING PLANT PRODUCT  
CONTAINING A NON-ENTERIC  
PATHOGEN ANTIGEN

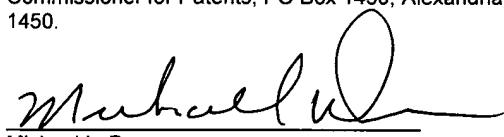
TC/Art Unit:1655

Examiner: Flood, Michele

Docket No.: RPP156CUS

### Certificate of Mailing by First Class Mail

I certify that this Amendment After Allowance Under Rule 312 is being deposited on JUNE 20,2006 with the U.S. Postal Service as first class mail under 37 C.F.R. §1.8 and is addressed to the Commissioner for Patents, PO Box 1450, Alexandria, VA 22313-1450.



Michael L. Dunn

### **REPLY BRIEF**

Mail Stop Appeal Briefs-Patents  
Commissioner for Patents  
PO Box 1450  
Alexandria, VA 22313-1450

Honorable Sir:

This is a reply brief in response to the Examiner's Answer of April 20, 2006.

At the outset, the Examiner's Answer is objected to in that it relies upon new arguments and newly cited references not previously discussed by the Examiner with respect to the 35 U.S.C. 112 rejections, e.g. Bratu et al., Titball et al., Stephenson and Farci et al. cited for the first time in support of the absence of known immunization against Rocky Mountain Spotted Fever, Hepatitis C, Dengue fever and Bubonic Plague and Pneumonic Plague. This is an improper new ground of rejection and if considered, the appeal should be withdrawn and a new non-final official action provided. As a further problem, copies of the newly cited documents have not been received by the attorney for the Applicants.

Further, the Examiner has not provided complete information with respect to the issue. It is true that a number of diseases may not have vaccines with FDA or WHO approval, but it is not

true that vaccines do not exist. In the current posture, to obtain approval, vaccines must have almost no side effects and no serious ones even in an extremely limited percentage of recipients. The vaccines that eliminated small pox and polio would almost certainly not have been approved today. That issue is not the same as whether vaccines can be made by those skilled in the art against the above diseases. They have been and were at the time the above application was filed. It is well established that the Patent Office is not the FDA and inventions are not restricted to what the FDA will or will not approve.

A number, if not all, of the references cited by the Examiner concede that at least some immunity can be conferred by known vaccines and seem principally concerned with side effects, an FDA issue.

Reference may be had to the following references showing the early existence of vaccines to diseases in question.

The Titball et all article in fact says with respect to plague vaccine "A live attenuated vaccine is also available. Whilst this vaccine is effective, it retains some virulence and in most countries is not considered to be suitable for use in humans."

An August 1979 article in "Infection and Immunity" by Kenyon et all indicates that an effective experimental vaccine was then available for Rocky Mountain spotted fever.

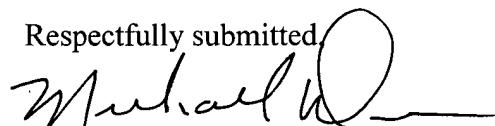
The Stephenson references cited by the Examiner only says that "commercial" dengue fever vaccines are not available. It does not say that there are no vaccines and in fact, as reported in June 26 2003 in the Fort Detrick Standard, a modern dengue fever vaccine was produced in the 1970's to early 1980's co-developed by GlaxoSmithKline Biologicals with the U.S. Army.

Copies of the above newly discussed references have not been provided since new references should not ordinarily be provided with a reply brief. It is again asserted that the Examiner's Answer is inappropriate for containing new grounds of rejection including both newly cited art and new arguments.

Attorney Docket No. RPP156CUS  
U.S. Patent Application No. 09/464,414  
Date: June 20, 2006

The application should be remanded to the Examiner for submission of a new non-final action to the Applicants along with copies of newly cited non-U.S. Patent art.

Respectfully submitted,



Michael L. Dunn  
Registration No. 25,330  
Simpson & Simpson, PLLC  
5555 Main Street  
Williamsville, NY 14221-5406  
Telephone No. 716-626-1564

MLD

Dated: June 20, 2006